

*CLAIM AMENDMENTS*

Claim 1. (Currently Amended) ~~Pharmaceutical~~ A pharmaceutical composition for oral administration, ~~containing~~ comprising at least one pharmaceutical active ingredient in an effective amount and comprising one or more coated particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, ~~characterized in that~~ wherein

(a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva or water, forms a coherent, mouldable, viscous, mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and release of active ingredient in the mouth, and

(b) the coating layer or the outermost of the coating layers contains an effective amount of at least one salivation-promoting agent.

Claim 2. (Currently Amended) ~~Composition~~ The composition according to claim 1, ~~characterized in that it contains~~ which comprises as hydratable polymer a nonionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25 °C, of from 3 to 10,000 mPa.s or an ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa.s.

Claim 3. (Currently Amended) ~~Composition~~ The composition according to claim 1 ~~or 2, characterized in that it contains~~ which comprises as hydratable polymer methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, sodium carboxymethylcellulose, polyacrylic acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, guar gum, hydroxypropyl-guar gum, gelatin and/or gum arabic.

Claim 4. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 3, characterized in that it contains~~ claim 1, which comprises a hydratable polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of at least about 25 mPa.s.

Claim 5. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 4 characterized in that~~ claim 1, wherein the hydratable polymer has an average particle size not exceeding 200 µm.

Claim 6. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 5, characterized in that~~ claim 1, wherein the coating is present in an amount of from 5 to 75% by weight, based on the essentially anhydrous composition.

Claim 7. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 6 characterized in that it contains~~ claim 1, which comprises as pharmaceutical active ingredient loperamide, mesalazine, olsalazine, cimetidine, ranitidine, famotidine, nizatidine, omeprazole, sucralfate, pantoprazole, pancreatin, bisacodyl, lactulose, acetylsalicylic acid, paracetamol, ibuprofen, morphine, tramadol, naproxen, diclofenac, piroxicam, terfenadine, astemizole, ambroxol, acetylcysteine, theophylline, atenolol, nifedipine, diltiazem, verapamil, isosorbide mononitrate, amitriptyline, nitrazepam, budesonide, ciprofloxacin, norfloxacin, ofloxacin, amoxicillin, cefaclor, cefadroxil, tetracycline, erythromycin, a pharmaceutically acceptable salt of one of these active ingredients or a combination of two or more of these active ingredients and salts.

Claim 8. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 7, characterized in that it contains~~ claim 1, which comprises as salivation-promoting agent a water-soluble organic acid or a water-soluble salt of a water-soluble organic acid and/or a water-soluble, osmotically active substance.

Claim 9. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 8, characterized in that it contains~~ claim 1, which comprises as salivation-promoting agent tartaric acid, citric acid, malic acid, ascorbic acid, a sodium or potassium salt of these acids, glucose, fructose, sucrose, xylitol, mannitol, sorbitol, maltitol or a combination of two or more of these compounds.

Claim 10. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 9 characterized in that~~ claim 1, wherein the coating consists of two or more layers, and the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in a layer of the coating is in each case no greater than the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in the adjacent inner layer of the coating.

Claim 11. (Currently Amended) ~~Composition~~ The composition according to claim

10, ~~characterized in that wherein~~ the outermost layer of the coating ~~contains~~ comprises a hydratable polymer with a viscosity of from 25 to 5000 mPa·s, and the second outermost layer of the coating ~~contains~~ comprises a nonionic hydratable polymer with a viscosity of from 5000 to 10,000 mPa·s and/or an ionic hydratable polymer with a viscosity of from 5000 to 30,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength ~~(weight-weight)~~ (weight/weight) aqueous solution of the polymer measured at 25°C.

Claim 12. (Currently Amended) ~~Composition~~ The composition according to claim 10 ~~or 11, characterized in that wherein~~ the outermost layer of the coating ~~contains~~ comprises polyvinylpyrrolidone or a cellulose ether with a viscosity of from 25 to 5000 mPa·s, and the second outermost layer of the coating ~~contains~~ comprises sodium carboxymethylcellulose with a viscosity of from 5000 to 8000 mPa·s, polyacrylic acid with a viscosity of from 5000 to 30,000 mPa·s or a cellulose ether with a viscosity of from 5000 to 10,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25 °C.

Claim 13. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 10 to 12, characterized in that~~ claim 10, wherein a hydratable polymer with an average particle size not exceeding 50 µm is used in the second outermost layer of the coating.

Claim 14. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 10 to 13, characterized in that~~ claim 10, wherein the second outermost layer of the coating is present in an amount of from 0.25 to 50% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous active ingredient-containing core, and the outermost layer of the coating is present in an amount of from 3 to 60% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous composition.

Claim 15. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 14, characterized in that~~ claim 10, wherein the core has a taste-masking coating layer which is resistant to gastric fluid or delays the release of active ingredient.

Claim 16. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 15, characterized in that~~ claim 1, wherein the coated particles have a maximum diameter of from 0.25 to 12 mm.

Claim 17. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 16, characterized in that it~~ claim 1, which comprises ~~contains~~ several coated particles, and the mouldable mass formed on contact with saliva causes the particles to stick together.

Claim 18. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 16, characterized in that it~~ claim 1, which consists of a single coated particle which has a maximum diameter of from 3 to 12 mm.

Claim 19. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 18, characterized in that it~~ claim 1, which is essentially anhydrous.

Claim 20. (Currently Amended) ~~Composition~~ The composition according to ~~any of claims 1 to 17, characterized in that it contains~~ claim 1, which comprises several coated particles and water in an amount of from 23 to 75% by weight, and is in the form of a single, coherent, viscous mass with sufficient consistency to allow it to be taken, without disintegrating, by hand or using a spoon or spatula.

Claim 21. (Currently Amended) ~~Process~~ A process for producing the pharmaceutical composition defined in ~~claims 1 to 20, characterized in that~~ claim 1, wherein one or more particles ~~containing~~ comprising at least one pharmaceutical active ingredient in an effective amount are coated with one or more layers, where ~~layers, where~~

(a) the layer or layers ~~contain~~ comprise at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva or water, forms a coherent, mouldable, viscous, mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and active ingredient being released in the mouth, and

(b) the layer or the outermost layer ~~contains~~ comprises an effective amount of at least one salivation-promoting agent, ~~in that, if required,~~ optionally the coated particles are converted with pharmaceutical ancillary substances into a pharmaceutical ~~dosage form presentation,~~ and ~~in that, if required~~ optionally, the composition is mixed with water

in an amount of up to about 300% by weight, based on the essentially anhydrous composition.

Claim 22. (Currently Amended) ~~Pharmaceutical~~ A pharmaceutical composition for oral administration, comprising one or more particles which ~~contain~~ comprise at least one pharmaceutical active ingredient in an effective amount, and a coherent, viscous, mass which is formed by contact with saliva, is slippery on the surface and does not adhere to the oral mucosa, which envelops the active ingredient-containing particle or the active ingredient-containing particles, and which prevents active ingredient-containing particles escaping from the mass and active ingredient being released in the mouth, and which [contains] comprises an effective amount of at least one salivation-promoting agent and at least one hydratable, pharmaceutically acceptable polymer in at least partly hydrated form.

Claim 23. (Currently Amended) ~~Medicinal~~ A medicinal product pack comprising a pharmaceutical composition according to ~~any of claims 1 to 20~~ claim 1 and the instructions that the composition be taken by direct administration into the mouth or, before intake, be mixed with a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous pharmaceutical composition.

Claim 24. (Currently Amended) ~~Method~~ A method for treating or preventing diseases by oral administration of a pharmaceutical composition, comprising the production of the pharmaceutical composition defined in claim 1, ~~claims 1 to 20, if required the addition of~~ and optionally adding a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous composition, and ~~direct administration of~~ directly administering the composition into the mouth.